MEDICAL POLICY – 7.01.104
Subtalar Arthroereisis

BCBSA Ref. Policy: 7.01.104
Effective Date: July 1, 2018
Last Revised: June 22, 2018
Replaces: N/A

RELATED MEDICAL POLICIES:
None

Introduction

The talus bone is the bone in the foot that joins with the two leg bones. It is commonly called the ankle bone. The talus sits on top of the heel bone (calcaneus), and the joint between the talus and calcaneus is called the subtalar joint. This joint is quite complex because it’s responsible for moving the foot in several different directions. If this joint is too flexible, it could result in conditions known as flat feet and talotarsal dislocation. Having flat feet means that when the foot is on the ground there is no space between the middle of the foot — the arch — and the ground. All of the foot touches the ground. Talotarsal joint dislocation causes the middle of the foot to roll inward during walking. In surgery to restrict the movement of the subtalar joint, a small piece of metal is screwed into the naturally occurring small channel between the ankle bone and the heel bone. The implant keeps the subtalar joint from moving too much. The studies on this surgery are small and don’t show how well this procedure works over the long term. Published studies also report problems from the surgery and a high number of implants being removed after they were put in. For these reasons, subtalar arthroereisis is considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

Service | Investigational
--- | ---
Subtalar arthroereisis | Subtalar arthroereisis is considered investigational.

**Note:** This policy only applies to subtalar arthroereisis (sinus tarsi implant or stent) surgery, a corrective operation to limit range of motion at the subtalar joint in cases of excessive mobility.

Arthrodesis describes a surgical fusion of a joint so that the bones grow together. Subtalar arthrodesis (joint fusion) surgery is not addressed in this policy.

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT</td>
<td>Extra-osseous subtalar joint implant for talotarsal stabilization</td>
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<tr>
<td>0335T</td>
<td>Extra-osseous subtalar joint implant for talotarsal stabilization</td>
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<td>HCPCS</td>
<td>Arthroereisis, subtalar</td>
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<td>S2117</td>
<td>Arthroereisis, subtalar</td>
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</table>

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Related Information

N/A

Evidence Review
Description

Arthroereisis is a surgical procedure that purposely limits movement across a joint. Subtalar arthroereisis (STA) or extraosseous talotarsal stabilization is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. Extraosseous talotarsal stabilization is also being evaluated as a treatment of talotarsal joint dislocation. It is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

Background

Flatfoot

Flexible flatfoot is a common disorder, anatomically described as excessive pronation during weight-bearing due to anterior and medial displacement of the talus. It may be congenital in nature, or it may be acquired in adulthood due to posterior tibial tendon dysfunction, which in turn may be caused by trauma, overuse, inflammatory disorders, and other factors. Symptoms include dull, aching pain, which in children may be described as growing pains. Additional symptoms include refusal to participate in athletics or walking long distances.

Treatment

Conservative treatments include orthotics or shoe modifications. Surgical approaches for painful flatfoot deformities include tendon transfers, osteotomy, and arthrodesis. Arthroereisis with a variety of implant designs has also been investigated.

Subtalar arthroereisis has been performed for more than 50 years, with a variety of implant designs and compositions. The Maxwell-Brancheau Arthroereisis (MBA) implant is the most frequently reported, although other devices such as the HyProCure, subtalar arthroereisis peg, and Kalix are also described in the medical literature. The MBA implant is described as reversible and easy to insert, with the additional advantage that it does not require bone cement. In children, insertion of the MBA implant may be offered as a stand-alone procedure, although children and adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities.
**Flatfoot**

Arthroereisis is the limitation of movement across a joint. Subtalar arthroereisis (also called extraosseous talotarsal stabilization) is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint.

**Talotarsal Joint Dislocation**

Extraosseous talotarsal stabilization is also being evaluated as a treatment of talotarsal joint dislocation. The stabilization procedure is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

**Summary of Evidence**

For individuals who have flatfoot or talotarsal joint dislocation who receive subtalar arthroereisis (STA), the evidence includes mainly single-arm case series and a small nonrandomized controlled trial comparing STA with lateral column calcaneal lengthening. Relevant outcomes are symptoms, functional outcomes, and quality of life. The small nonrandomized comparative trial (N=24 feet) is considered preliminary, and interpretation of the case series evidence is limited by the use of adjunctive procedures in addition to STA, creating difficulties in determining the extent to which each modality contributed to the outcomes. Another limitation of the published data is the lack of long-term outcomes, which is of particular importance because the procedure is often performed in growing children. Also, some studies have reported high rates of complications and implant removal. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in March 2018 did not identify any ongoing or unpublished trials that would likely influence this review.
Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2012 Input

In response to requests, input was received through 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2012. Input was mixed, with most reviewers considering this procedure to be investigational.

2009 Input

In response to requests, input was received through 1 physician specialty society (3 reviews) and 5 academic medical centers while this policy was under review in 2009. Input was mixed regarding the medical necessity of arthroereisis.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

Guidance from the National Institute for Health and Care Excellence (2009) concluded that current evidence on the safety and efficacy of sinus tarsi implant insertion for mobile flatfoot is inadequate in quality and quantity.\(^\text{15}\)

American College of Foot and Ankle Surgeons

The American College of Foot and Ankle Surgeons (ACFAS) published practice guidelines for the diagnosis and treatment of adult and pediatric flatfoot in 2004 and 2005 (neither is included in the ACFAS library of current clinical practice guidelines).\(^\text{16,17}\)
The ACFAS guidelines on adult flatfoot have stated:

In the adult, arthroereisis is seldom implemented as an isolated procedure. Because of the long-term compensation and adaptation of the foot and adjunctive structures for flatfoot function, other ancillary procedures are usually used for appropriate stabilization. Long-term results of arthroereisis in the adult flexible flatfoot patient have not been established. Some surgeons advise against the subtalar arthroereisis procedure because of the risks associated with implantation of a foreign material, the potential need for further surgery to remove the implant, and the limited capacity of the implant to stabilize the medial column sag directly.

ACFAS guidelines on pediatric flatfoot have stated: “proponents of this procedure (arthroereisis) argue that it is a minimally invasive technique that does not distort the normal anatomy of the foot. Others have expressed concern about placing a permanent foreign body into a mobile segment of a child’s foot. The indication for this procedure remains controversial in the surgical community.”

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

A number of implants have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process and are summarized in Table 1. In general, these devices are indicated for insertion into the sinus tarsi of the foot, allowing normal subtalar joint motion while blocking excessive pronation.

Table 1. Representative Subtalar Implant Devices Cleared by FDA

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtalar MBA®</td>
<td>Integra LifeSciences</td>
<td>07/96</td>
<td>K960692</td>
</tr>
<tr>
<td>OsteoMed Subtalar Implant System</td>
<td>OsteoMed</td>
<td>08/03</td>
<td>K031155</td>
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<tr>
<td>BioPro Subtalar Implant</td>
<td>BioPro</td>
<td>09/04</td>
<td>K041936</td>
</tr>
<tr>
<td>Device</td>
<td>Manufacturer</td>
<td>Date Cleared</td>
<td>510(k) No.</td>
</tr>
<tr>
<td>--------------------------------------------</td>
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</tr>
<tr>
<td>HyProCure Subtalar Implant System</td>
<td>Graham Medical Technologies</td>
<td>09/04</td>
<td>K042030</td>
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<tr>
<td>MBA resorb Implant</td>
<td>Kinetikos Medical</td>
<td>09/05</td>
<td>K051611</td>
</tr>
<tr>
<td>Metasurg Subtalar Implant</td>
<td>Metasurg</td>
<td>05/07</td>
<td>K070441</td>
</tr>
<tr>
<td>Subtalar Implant</td>
<td>Biomet Sports Medicine</td>
<td>07/07</td>
<td>K071498</td>
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<tr>
<td>Arthrex ProStop Plus Arthroereisis Subtalar Implant</td>
<td>Arthrex</td>
<td>01/08</td>
<td>K071456</td>
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<tr>
<td>Trilliant Surgical Subtalar Implant</td>
<td>Trilliant Surgical</td>
<td>02/11</td>
<td>K103183</td>
</tr>
<tr>
<td>Metasurg Subtalar Implant</td>
<td>Metasurg</td>
<td>08/11</td>
<td>K111265</td>
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<tr>
<td>NuGait™ Subtalar Implant System</td>
<td>Ascension Orthopedic</td>
<td>08/11</td>
<td>K111799</td>
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<td>Disco Subtalar Implant</td>
<td>Trilliant Surgical</td>
<td>12/11</td>
<td>K111834</td>
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<tr>
<td>OsteoSpring FootJack Subtalar Implant System</td>
<td>OsteoSpring Medical</td>
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<td>K112658</td>
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<tr>
<td>IFS Subtalar Implant</td>
<td>Internal Fixation Systems</td>
<td>12/11</td>
<td>K113399</td>
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<tr>
<td>The Life Spine Subtalar Implant System</td>
<td>Life Spine</td>
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<td>K160169</td>
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FDA: Food and Drug Administration

* FDA 510(k) database search product code HWC (03/08/18)

References


<table>
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<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<td>04/11/05</td>
<td>Add to Surgery Section - New Policy</td>
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<tr>
<td>06/09/06</td>
<td>Disclaimer and Scope update - No other changes</td>
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<tr>
<td>08/14/07</td>
<td>Replace policy - Policy updated with literature review; references added. No change in policy statement.</td>
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<tr>
<td>01/17/08</td>
<td>Code Updated - CPT code 28725 was removed and added 28735.</td>
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<tr>
<td>06/10/08</td>
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<tr>
<td>10/13/09</td>
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<td>Replace policy - Policy updated with literature review through July 2010; references added and reordered. The policy statement remains unchanged.</td>
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<tr>
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<td>06/04/12</td>
<td>Codes updated; CPT 28725 and 29907 removed from the policy as they do not apply.</td>
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<td>11/27/12</td>
<td>Replace policy - Policy guidelines revised with addition of clarification for Arthroereisis (joint implant) surgery vs. Arthrodesis (joint fusion) surgery. Rationale section revised based on literature review through June 2012 and; clinical input. References 2, 3, 10, 14-16 added; others renumbered or removed. Policy statement unchanged.</td>
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<td>12/04/13</td>
<td>Replace policy. A literature review through August 13, 2013 did not prompt the addition of any new references. Policy statement unchanged. Codes 0335T (new code), 28735 and 28899 added to the policy.</td>
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<tr>
<td>03/11/14</td>
<td>Coding Update. Code 81.18 was removed per ICD-10 mapping project; this code is not utilized for adjudication of policy.</td>
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<tr>
<td>06/01/16</td>
<td>Annual Review, approved May 10, 2016. Policy statement unchanged. Literature review, no references added. Removed code 28725; it doesn’t apply to this policy.</td>
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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD) Complaint forms are available at

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